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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,059	12/29/2003	Kevor Tenhuisen	ETH-5119	8329

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EXAMINER	
DORNBUSCH, DIANNE	
ART UNIT	**PAPER NUMBER**
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,059	TENHUISEN ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The indicated allowability of claim 9 is withdrawn in view of the newly discovered interpretation of the reference to Mikus et al. (2002/0151967). Rejections based on the new interpretation of the reference follow.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikus et al. (2002/0151967).

Mikus discloses the following claimed limitations:

Claim 1: An apparatus for compressing a stent having at least one protrusion, comprising: a mandrel (114) insertable into a lumen of the stent (110) for holding the stent (Fig. 14); a protrusion compressor (combination of the part 115 including the handle 118 and 116 including handle 119) coupled to said mandrel (Fig. 4), said mandrel rotatable relative to said protrusion compressor ([0087] Lines 10-11), said protrusion compressor having a tab (the hook in Fig. 14) extending therefrom towards said mandrel, said tab (the hook seen in Fig. 14 is pressing on one protrusion of the stent) pressing the at least one protrusion of the stent inwardly toward the lumen of the stent when said mandrel is rotated relative to said protrusion compressor ([0096] Lines

8-12 where as the rotation is making the stent expand it can also make it contract), said protrusion compressor having a grip portion (119) with a hub (116 is the sheath assembly as referred to in the reference) and a collar (115 is the outer catheter assembly as referred to in the reference), said collar coaxially received on said hub (Fig. 14) with said tab extending therefrom at a distal end thereof (Fig. 14 where the tap is in the distal end of the collar), said collar moveable telescopically on said hub between a retracted position and a deployed position (Fig. 13), said hub having a relief slot (distal opening at the end of the tube of 116) on a distal end thereof (Fig. 13-14), said tab alignable with said relief slot when said collar and tab are in the deployed position (Fig. 13-14), said tab capturing the at least one protrusion of the stent between said tab and said relief slot when said apparatus compresses the at least one protrusion (Fig. 13).

Claim 2: That said mandrel (114) extends through said protrusion compressor coaxially (Fig. 13-14).

Claim 3: That the apparatus further comprising a knob (117) disposed on an end of said mandrel to aid in turning said mandrel and for retaining said protrusion compressor on said mandrel ([0096] Lines 9-10).

Claim 13: An apparatus for compressing a coiled stent (110) having at least one external protuberance, comprising: means for holding the stent (112 which is the stent segment, with gap/hook 127 of component 114 seen in Fig. 14); means for capturing (combination of 115 and 116) the at least one external protuberance (Fig. 14), including a tab (the hook in Fig. 14) and an opposable slot (the opening at the distal end of 116) between which the at least one external protuberance can be captured (Fig. 13), said

means for capturing being rotatably coupled to said means for holding ([0087] Lines 10-11), such that relative rotation thereof compresses the at least one protuberance ([0096] Lines 8-12 where as the rotation is making the stent expand it can also make it contract).

Claim 14: That the apparatus further comprising, means for gripping (117) said means for holding the stent to aid in rotating said means for holding relative to said means for capturing ([0096] Lines 9-10).

Claim 15: The apparatus further comprising, means for gripping (119) said means for capturing the stent (Fig. 13-14).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mikus et al. (2002/0151967).

Claim 4:

Mikus discloses that said mandrel (114) has a stent fixation zone (112) with an outer diameter approximating the interior diameter of at least a portion of the lumen of the stent ([0089] Lines 1-5) and frictionally engaging the stent (110) when the stent (110) is placed on the mandrel (114) over the stent retention zone (112). The stent is

placed on the mandrel where it has to have frictional engagement since both parts are touching each other as seen in Fig. 13.

Mikus discloses the claimed invention except for the stent fixation zone having an outer diameter greater than the interior diameter of a portion of the lumen of the stent prior to installation of the stent on the mandrel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a slightly greater diameter, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim 6: That said protrusion compressor is captured between said knob (117) and said stent retention zone (112) as seen in Fig. 14.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mikus et al. (2002/0151967) in view of Frantzen (6,042,606).

Mikus teaches all the claimed limitations discussed above however, Mikus does not disclose that said mandrel has a tapered end.

Frantzen discloses that said mandrel (M) has a tapered end (T in Fig. 11) (Col, 9 Lines 65-67).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with the tapered mandrel in view of the teachings of, in order to ease the placement of the stent on the mandrel by sliding the stent through the tapered portion.

7. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mikus et al. (2002/0151967) in view of Scarborough et al. (5,928,238).

Claim 7:

Mikus discloses all the claimed limitation discussed above including a restrainable component (139) which prevents the longitudinal movement of the mandrel with respect to the collar.

Mikus discloses the claimed invention except for the restrainable component being between the hub and collar in order to prevent the longitudinal movement of the two. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the restrainable member between the collar and hub, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Mikus teaches all the claimed limitations discussed above however, Mikus does not disclose in this embodiment that the collar restrained from rotating relative to said grip portion by a pin extending therethrough and into an elongated slot in said hub nor that said slot and pin constraining the collar to telescopic movement on said hub along a length of travel limited by said slot.

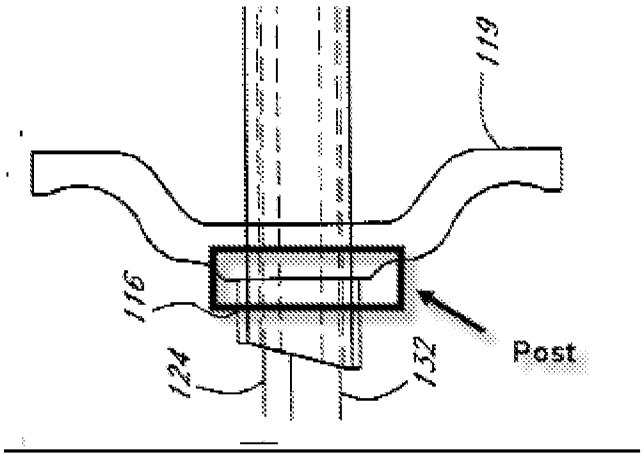
Scarborough discloses a collar (322) restrained from rotating relative to said grip portion (the proximal end of part 324) by a pin (326) extending therethrough and into an elongated slot (328) in said hub (324) and said slot and pin constraining the collar to telescopic movement on said hub along a length of travel limited by said slot (Col. 6 Lines 58-61).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with a pin and slot on the hub instead of the restrictable member in view of the teachings of Scarborough, in order to prevent movement of the device that would cause the accidental deployment of the stent.

Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with a pin and slot on the hub instead of the restrictable member since it is well known in the art that pin-slot combination is used as a way to control the movement of two piece in any desired direction.

Claim 8: Mikus discloses that said collar has a flange (the proximal end 118) extending outwardly therefrom for a user to grip said collar to aid in deployment and retraction of said tab (Fig. 14 and [0087] Lines 14-15).

Claim 9: Mikus discloses all the claimed limitations discussed above (see rejection of claims 1-4 and 6-8) including that said grip portion (119) has a hollow post (see figure below) extending from said hub (Fig. 13), said post having a relief slot (the distal opening of the post) on a distal end thereof (see figure below), said relief slot positioned on said post to align with said tab when said tab is in the deployed position (Fig. 13-14), said tab capturing the at least one protrusion of the stent between said tab and said relief slot when said apparatus compresses the at least one protrusion (Fig. 13).
Note that the relief slot of claim 1 is on said hub and not and said post. The post is not claimed in claim 1 therefore a different release slot in the same reference was used.



Claim 10:

Mikus discloses that the apparatus further includes a rotational inhibitor disposed between said grip portion and said collar, said rotational inhibitor controlling the relative rotation ([0087] the last 5 lines). The rotational inhibitor can be different kinds of locking mechanisms such as a keyway structure.

Mikus teaches all the claimed limitations discussed above however, Mikus does not disclose the apparatus includes a ball and detent interface.

The ball and detent interface is well known in the art as a useful locking mechanism which can be use to inhibit the rotation of the device. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Mikus with a ball and recess mechanism in order to inhibit the rotation of the device as well as a locking mechanism to prevent an early deployment of the stent.

Claim 11: Mikus discloses different kinds of stents that can be used with the device. One such stent is stent 10 which has the at least one protrusion of the stent (33 and 54) is at least one enlarged coil (33 and 54 in Fig. 8) disposed at an end of the stent (Fig.

8). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add the coil (33 and 54) on stent 10 (and stent 110) in order to prevent the deployed stent in the urethra from obstructing the sphincter.

Claim 12: The apparatus further including a sleeve (the tube extending from part 116 can act as a sleeve) extending from said collar distal to said flange (Fig. 14), said tab (the hook in Fig. 14) extending from said sleeve. The tab extends from the sleeve as seen in Fig. 14 where it is distally from the distal end of the sleeve.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773